IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

UNITED STATES OF AMERICA		|	
		|	
		|	
v.		|	**No. 3:15-cr-00496-L**
		|	
USPLABS, LLC	**(1)**	|	
JACOBO GEISSLER	**(2)**	|	
JONATHAN DOYLE	**(3)**	|	
MATTHEW HEBERT	**(4)**	|	
S.K. LABORATORIES, INC.	**(5)**	|	
SITESH PATEL	**(6)**	|	

DEFENDANTS USPLABS, LLC, JONATHAN DOYLE, JACOBO GEISSLER, MATTHEW HEBERT, S.K. LABORATORIES, INC. AND SITESH PATEL'S REPLY TO THE GOVERNMENT'S RESPONSE TO DEFENDANT'S MOTION TO DISMISS COUNT TEN

There is nothing procedurally improper about Defendants' Motion and the Government fails to adequately charge a violation of the adulteration statute. Thus, the Court should grant Defendants' Motion to Dismiss Count Ten.

I. THERE IS NOTHING PROCEDURALLY IMPROPER ABOUT DEFENDANTS' MOTION.

Federal Rule of Criminal Procedure 7(c)(1)—and the U.S. Constitution—require more than a bare recitation of the statute under which Defendants have been charged. U.S. Const. amend. V, VI; Fed. R. Crim. P. 7(c)(1). Rather, they require inclusion of "all the material facts and circumstances." *United States v. Hess*, 124 U.S 483, 486 (1888); *see Russell v. United States*, 369 U.S. 749, 765 (1962) (internal quotation marks omitted) (indictments must "descend to particulars"). Providing factual bases for allegations of criminality is especially important where, as here, the statute's language lacks specificity. *See Alabama Packing Co. v. United States*, 167 F.2d 179, 181-82 (5th Cir. 1948) (reversing conviction where indictment was a "mere

conclusion of the pleader" that did not allege "facts essential to constitute the offense charged"); *Boykin v. United States*, 11 F.2d 484, 485 (5th Cir. 1926) ("where a statute is general, it is not sufficient merely to follow its language in an indictment"); *see also United States v. Schmitz*, 634 F.3d 1247, 1261-62 (11th Cir. 2011) (dismissing counts where indictment did not allege facts or circumstances informing defendant of specific charges).

The Government's Response does not distinguish any of these cases cited by Defendants, *supra*. *See* Gov't Resp. to Defs.' Mot. To Dismiss Count Ten (Dkt #220), Dkt #239 ("Gov't Resp."). Instead, the Government attempts to recast Defendants' Motion as challenging the sufficiency of the evidence. Gov't Resp. at 1-2. In so doing, it conflates ***evidence*** with ***allegations***; although the Government is not required to prove facts at this stage, it is required to allege them. As discussed below, its failure to do so sufficiently warrants dismissal.

II. THE GOVERNMENT DOES NOT ADEQUATELY CHARGE ADULTERATION.

A. The Indictment Fails To Allege Any Facts Supporting That OEP-NF Presented "A Significant Or Unreasonable Risk To Consumers Under The Conditions Of Use Recommended Or Suggested In The Labeling."

The Government claims that Count Ten adequately charges a violation of § 342(f)(1)(A)(i) because of the mere inclusion of quoted language of the statute. Gov't Resp. at 4. However, as argued in Defendants' Motion, an indictment may still be defective, even where it tracks the language of the criminal statute, where the statute's prohibition is described in general terms. *See Boykin v. United States*, 11 F.2d 484, 485 (5th Cir. 1926) ("[w]here a statute is general, it is not sufficient to merely follow its language in an indictment, but the indictment must allege the specific offense coming under the general description of the statute, in order that the accused may enjoy the right, secured by the Sixth Amendment, 'to be informed of the nature and cause of the accusation' against him."). Although the Government argues that a parroting of

the statutory language alone should suffice here, the cases on which it relies for this proposition, *United States v. Gordon* and *United States v. Thomas*, are easily distinguishable.

In *Gordon*, defendant appealed his conviction, contending that the indictment was insufficient. 780 F.2d 1170-72. For conspiracy and fraud charges, the indictment tracked the language of the statute and stated particular facts for each offense, including the time, place, purpose of the offense, and names of the persons involved. *Id*. at 1171-72 & n.3. As a result, the court held that the indictment adequately conformed to minimal constitutional standards, distinguishing "a defendant's constitutional *right* to know the offense with which he is charged" from "a defendant's *need* to know the evidentiary details." *Id*. Defendants, however, are not seeking dismissal of Count 10 for lack of "evidentiary details"; rather, they do so for lack of sufficient factual allegations supporting the Count. Moreover, the court in *Gordon* in any event found that the indictment not only tracked the language of the conspiracy and mail/wire fraud statutes, but also "set[] forth particular facts constituting each offense," as it alleged the specific acts constituting the criminal violations. *Gordon*, 780 F.2d at 1171.

Moreover, in *Thomas*, the defendant challenged his conviction for conspiracy to possess crack cocaine with intent to distribute, alleging that the district court erred in not quashing the count because the indictment failed to identify a co-conspirator or include the words "and others known and unknown to the grand jury." 348 F.3d at 81-82. The court found that the indictment sufficiently set forth the elements of a conspiracy because the government used the statutory language—which is *generally*, but not always, sufficient—and because involvement of another person was implicit in that language. 348 F.3d at 84. The failure in *Thomas* to allege the existence of a co-conspirator in an indictment reciting the language of the federal conspiracy statute is a far cry from the sparsity of alleged facts supporting Count 10 here.

Indeed, the allegations relating to elements of Count 10 are either deliberately vague or non-existent. The Indictment ambiguously alleges an "association" between "an outbreak of liver injuries" and "USPlabs products containing aegeline." First Superseding Indictment, Dkt #95, ¶ 33 ("Indictment"). This allegation tellingly fails to allege that this association involved OEP-NF specifically, or whether it involved other of the multiple aegeline-containing products USPlabs had on the market at the time (none of which is alleged to be adulterated). Moreover, even if the Indictment could be read to allege that the purported outbreak victims consumed OEP-NF specifically, there is ***not a single allegation*** that any did so "under conditions of use recommended or suggested in the labeling," which is an essential element of § 342(f)(1)(A)(i).[1] This absence of factual allegations suggests that the grand jury could not have determined probable cause of Count 10. *See United States v. Outler*, 659 F.2d 1306, 1311 (5th Cir. 1981) ("Unless ***every element of an offense*** appears in the indictment, it is impossible to assure the defendant that a grand jury properly determined probable cause of the offense.") (emphasis added).

While the Government finds it "hard to imagine how [it] could charge a violation of this provision other than by simply alleging that the supplement presented risks 'under the conditions of use recommended or suggested in the labeling,'" Gov't Resp. at 4-5, doing so is not difficult when one has supporting evidence. For example, the Indictment could have contained allegations that the consumers with injuries allegedly "associated" with USPlabs' aegeline-containing products used OEP-NF specifically, and, as recommended on its labeling, (1) were healthy

[1] The Government also suggests that it intends to prove at trial that Defendants may not have intended that consumers follow the suggestions and recommendations in OEP-NF's labeling. Gov't Resp. at 5 n.2. This is an entirely new allegation that appears nowhere in the Indictment, and the Government cites no evidence whatsoever to support it. Moreover, the Government's reliance upon *Storage Spaces* to support this novel legal theory is utterly misplaced: *Storage Spaces* is a case about whether the substance at issue fell within the FDCA's definition of a "drug," where the defendant's intended use of the substance in question "is the key element in this statutory definition." *United States v. Storage Spaces Designated Nos. 8 & 49 Located at 277 E. Douglas, Visalia, Cal.*, 777 F.2d 1363, 1366 (9th Cir. 1985).

adults, (2) did not consume it "in combination with caffeine or other stimulants," (3) did not combine it with alcohol or use it "under extreme conditions of heat, sleep deprivation or dehydration," and (4) consulted with a physician before using it. *See* Mot. To Dismiss, Dkt #220 at 15. The Indictment does not allege any of these things for any alleged victim; it does not allege any victim's adherence to OEP-NF's recommended/suggested use ***even in conclusory terms***. This omission renders the Indictment insufficient under Rule 7(c)(1) and the U.S. Constitution.[2]

B. The Government's New Post-Indictment "Mix Of Ingredients" Theory Of Adulteration Illustrates The Indictment's Failure To Provide Defendants With Sufficient Notice Of The Charge.

The insufficient level of factual detail in the Indictment – and its failure to provide Defendants with fair notice of the nature of the charge in Count 10 – has been put into sharp relief by the Government's recently filed Notice of Expert Testimony, Dkt #222 ("Gov't Disclosure"). That Disclosure makes clear that the Government has shifted its theory of adulteration from that suggested in the Indictment (*i.e.*, that the aegeline contained in OEP-NF was "associated" with the purported outbreak of liver injuries) to one that fails to identify any specific toxic agent or specific combination of toxic agent and instead points to OEP-NF's "mix of ingredients" as "***perhaps***" the cause of the alleged liver injuries.

One purpose of the specificity requirement under the Federal Rule of Criminal Procedure 7(c)(1) and the Fifth and Sixth Amendments is to ensure that the grand jury determined that there was probable cause to charge a crime. *See Outler*, 659 F.2d at 1311; *see also Russell*, 369 U.S.

[2] The Government's reliance on *McGough* for the proposition that it is "fair to infer" that these consumers used OEP-NF under its recommended or suggested use is misplaced. In rejecting the challenge to the sufficiency of the indictment, the court in *McGough* found it unnecessary "for the indictment to allege *an array of facts* which would enable [the court] to *conclusively determine* whether the false statement was material." 510 F.2d 598, 602 (5th Cir. 1975) (emphases added). Here, it is not that the Indictment fails to allege *an array of facts* to be able to make a *conclusive determination* regarding an element of the violation charged in Count Ten; instead, there are ***no*** facts regarding that element.

at 770-71 ("'If it lies within the province of a court to change the charging part of an indictment to suit its own notions of what it ought to have been or what the grand jury would probably have made it if their attention had been called to suggested changes, the great importance which the common law attaches to an indictment by a grand jury, as a prerequisite to a prisoner's trial for a crime, and without which the Constitution says 'no person shall be held to answer,' may be frittered away until its value is almost destroyed.") (citation omitted). However, the Government's most recent theory of adulteration is inconsistent with the allegations on which the grand jury indicted Defendants, and illustrates the lack of notice this Indictment provides.

Although the Indictment lacks specificity in a number of respects, it does make clear that the grand jury indicted based on a theory presented by the Government that the aegeline in OEP-NF was "associated" with the alleged liver injuries. The Indictment alleges that "one of the synthetic test chemicals that USP Labs imported from China was called 'aegeline,'" and that "[t]he first aegeline-containing version of OxyElite Pro, which was called OxyElite 'New Formula' (also called 'Super Thermo' and Purple Top'), went on sale in or around December 2012." Indictment at ¶¶ 28-29. It further alleges that "[i]n fall 2013, shortly after OxyElite Pro Advanced Formula went on sale, an outbreak of liver injuries was associated with USPlabs' products ***containing aegeline***," and that during the alleged outbreak, "Geissler quickly instructed that . . . ***aegeline*** be removed from the product formula going forward." Indictment at ¶ 33, 35 (emphases added).[3] The Government continues to advance this theory in the Response, stating

[3] This was the same theory that the FDA touted in its public statements from the time of the outbreak until at least seven months later, and that the Government's proposed expert, Dr. Herbert Bonkovsky, touted before a national television audience in an episode of PBS's Frontline in January 2016, three months after the Indictment. *See* Mot. To Exclude Bonkovsky at 11, n14.

that "[t]he factual recitation in the instant indictment details the defendants' creation of OxyElite Pro New Formula ("OEP-NF") with synthesized ingredients from China." Gov't Resp. at 3.[4]

However, the Government's Expert Notice abandons the aegeline theory and replaces it with a novel and scientifically unsupported "mix of ingredients" theory of adulteration. Dr. Herbert Bonkovsky, one of the Government's proposed experts, has apparently concluded that although "the specific, individual toxic agents that were contained in OEP-NF and that were responsible for the acute liver injury remain uncertain based on the current published, peer-reviewed research, . . . [i]n any case, to a reasonable degree of medical certainty, the mix of ingredients in OEP-NF was responsible for acute, severe, and sometimes fatal injury . . . ." Gov't Disclosure at 10. Dr. Bill J. Gurley, another of the Government's proposed experts, similarly states that "the combination of ingredients present in OEP-NF, and not one particular compound, rendered the product hazardous," and "the fact that the ingredients of OEP-NF may not be specifically toxic when administered separately has little, if anything, to say about the toxicity of the multi-ingredient compound." *Id*. at 25, 26.

This is precisely why Rule 7(c)(1) requires more than just a recitation of the statutory language here. As described in their own expert disclosure, Defendants based their expert designations on its best reading of the Indictment's allegations—namely, that the adulteration of

[4] There is nothing illegal about using synthetic versions of botanical counterparts. Longstanding FDA policy has treated synthetic copies of dietary ingredients as dietary ingredients, and there is no support in the FDCA for treating them differently. *See, e.g.*, Ex. 1 (Dec. 22, 2011 letter from Orrin G. Hatch and Tom Harkin to M. Hamburg, FDA Commissioner, stating "the draft guidance attempts to assert that synthetic copies of botanicals can never be a dietary ingredient, an assertion that is wholly without statutory basis, and in fact contradicts long-standing FDA policy."); *see also* Answer to Hi-Tech Pharmaceuticals, Inc.'s Complaint, *United States v. Undetermined Quantities of All Articles of Finished and In-Process Foods et al.*, No. 13-3675 (N.D. Ga. filed May 5, 2015), Dkt #52, at 6 (Government's admission that it "has recognized the equivalence of synthetic and natural vitamins, and that the FDA has recognized that both synthetic and natural ingredients used in the food supply many be dietary substances and, therefore, dietary ingredients"). The Government also misleadingly suggests that OEP-NF was adulterated because Defendants shipped aegeline into the country using a false name. That fact, even if true, could not by itself render OEP-NF adulterated under § 342(f)(1)(a)(i). Moreover, any false identification of aegeline was immaterial to it being permitted entry into the country, as the Government expressly permitted the entry of aegeline into the United States, including by Defendants, when accurately identified in accompanying documentation. Ex. 2.

OEP-NF was due to its inclusion of aegeline.[5] Dkt #232, at 1-2. An indictment that permits the Government to switch its scientific theory of adulteration at this late stage is the opposite of fair notice. Indeed, when Defendants asked for more specificity regarding the Government's theory of adulteration prior to the submission of the parties' expert disclosures, the Government refused to provide that information. *See, e.g.*, Ex. 3. Although the Government argues that the expert testimony provides additional details regarding the alleged injuries "associated" with OEP-NF, the Disclosure cannot cure a defective indictment retroactively. *Russell*, 369 U.S. at 770 (noting the "settled rule in the federal courts that an indictment may not be amended except by resubmission to the grand jury, unless the change is merely a matter of form").[6]

Moreover, the absence of any allegation regarding a "multi-ingredient" theory in the Indictment leaves it unclear whether the grand jury indicted Defendants based on evidence that OEP-NF's risk to consumers was a result of its "mix of ingredients," rather than of its use of aegeline. This is an additional reason for dismissal. *Russell*, 369 U.S. at 770 ("To allow the prosecutor, or the court, to make a subsequent guess as to what was in the minds of the grand jury at the time they returned the indictment would deprive the defendant of a basic protection which the guaranty of the intervention of a grand jury was designed to secure. For a defendant

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[5] The Government makes much of Defendants' Statement Regarding Expert Testimony, Dkt #120, which was provided based on Defendants' best reading of the basis for Count Ten. However, Defendants made clear their assumption that "the Government will follow the lead of plaintiff's attorneys, who have already bought lawsuits against Defendants and have sought to qualify people as experts to argue to the contrary," Dkt #120, at 2, all of whom have alleged that they were harmed because of the aegeline contained in OEP NF. *See, e.g.*, Complaint at ¶¶ 45, 50, *Waikiki v. USPlabs et al.*, (D. Haw. 2013) (No. 1:13-cv-639-KSC) ("USP used new, synthetic, untested and dangerous ingredients, including without limitation the untested, synthetic and illegal ingredient aegeline. On October 11, 2013, the FDA issued a warning letter to USP indicating that aegeline (N-[2-hydroxy-2(4-methoxyphenyl) ethyl]-3-phenyl-2-propenamide), an ingredient in OxyElite Pro Super Thermo, was a new dietary ingredient that lacked evidence of safety.").

[6] The Government cites *United States v. Moody*, 923 F.2d 341, 351 (5th Cir. 1991), to support its contention that material beyond the Indictment "has given the defense fair notice of the charge," as if these materials somehow absolve the Government of meeting the required level of specificity in the Indictment. Gov't Resp. at 6. However, *Moody* addressed not whether the indictment in that case was sufficient, but whether the defendant was entitled to a bill of particulars, and is thus inapposite here.

could then be convicted on the basis of facts not found by, and perhaps not even presented to, the grand jury which indicted him.").

C. Without A Formal Administrative Determination That Aegeline Or OEP-NF Was Adulterated, Count 10 Must Be Dismissed.

The Government brushes aside the DSHEA Senate Report indicating that formal rulemaking is required under § 342(f)(1)(A)(i), arguing that it should not be considered based on language by DSHEA's sponsors and because the Senate Report was based on a non-final version of the law. However, DSHEA's legislative history, including the Senate Report cited by Defendants, has been considered by other courts in construing DSHEA. *Nutraceutical Corp v. Von Eschenbach*, 459 F.3d 1033, 1039 n.5 (10th Cir. 2006) (approving of the district court's use of legislative history in evaluating DSHEA); *Pharmanex v. Shalala*, 221 F.3d 1151, 1158 (10th Cir. 2000) (considering legislative history of DSHEA despite Statement of Agreement, including S. Rep. No. 103-410); *see also Alliance for Natural Health U.S. v. Sebelius*, 775 F. Supp. 2d 114, 128-30 (D.D.C. 2011) (noting Statement of Agreement, but nonetheless considering S. Rep. No. 103-410). Thus, examination of the legislative history, including relating to previous drafts of a statute, is indicative of congressional intent when examining the meaning of a statute even when, as here, certain members seek to alter the weight of that history through subsequent statements into the legislative record.[7]

Moreover, the structure of § 342(f)(1)(A)(i) as a whole confirms the legislative intent reflected in that legislative history. At the end of subparagraph 1 of § 342(f), the statute provides that [i]n any proceeding under this subparagraph, the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated." 21 U.S.C. § 342(f). Congress

[7] *See Aguillard v. Edwards*, 765 F.2d 1251, 1256 (5th Cir. 1985), *aff'd*, 482 U.S. 578 (1987) (noting that "the remarks of the sponsor or author of a statute [do not] control our determination of legislative purpose"); *CSPC v. GTE Sylvania, Inc*., 447 U.S. 102, 118 (1980) (noting that "the views of a single legislator, even a bill's sponsor, are not controlling").

need not have made clear that the Government has the burden of proving all of the elements of adulteration under this subparagraph in a criminal proceeding; that the Government holds the burden of proof in criminal cases is a bedrock principle of criminal law that is not (and need not) be spelled out in this or any other federal criminal statute. This provision is thus a strong indication that in enacting § 342(f), Congress contemplated in each instance a proceeding ***other than a criminal proceeding*** in which the Government has the burden to prove adulteration.

Finally, the inherent balancing of risks against benefits used to determine whether a dietary supplement presents an "unreasonable" or "significant risk" is further evidence that § 342(f)(1)(A)(i) requires an administrative determination of adulteration. Ephedrine is illustrative; although there have been criminal charges and convictions for distributing ephedrine-containing products, all such matters were brought after FDA made a formal determination that ephedrine was adulterated. *See* 21 C.F.R. § 119.1 (finding ephedrine adulterated); *Nutraceutical Corp.*, 459 F.3d at 1039. In so finding, the FDA undertook, as the statute requires, a "risk/benefit analysis to ascertain whether the risks of the product outweigh its benefits." 69 Fed. Reg. 6788, 6798 (2004); *see also Nutraceutical Corp*., 459 F.3d at 1039. This need for regulatory balancing is further evidence that a finding of adulteration under § 342(f)(1)(A)(1) requires a regulatory determination that an ingredient or product is adulterated before criminal enforcement can proceed.[8]

[8] Indeed, Defendants have been unable to identify any criminal enforcement actions brought under § 342(f)(1)(A)(i) other than actions based on ephedrine brought after the FDA's adulteration determination.

III. CONCLUSION

For the foregoing reasons, Count Ten of the Indictment should be dismissed.

Respectfully submitted:

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CERTIFICATE OF SERVICE

On June 8, 2017, I electronically submitted the foregoing document with the clerk of the court of the U.S. District Court, Northern District of Texas, using the electronic case filing system of the court. I hereby certify that I have served all counsel of record electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2),.

/s/ Richard B. Roper
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